REMARKS

The Examiner has rejected Claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Pub. No. 2003/0100932 to Ciaff ("Ciaff") in view of U.S. Patent No. 5,775,331 to Raymond et al. ("Raymond") and U.S. Patent No. 6,685,729 to Gonzalez ("Gonzalez"). The Examiner has also rejected Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Ciaff in view of Raymond and Gonzalez, and further in view of U.S. Patent No. 4,817,628 to Zealear et al. ("Zealear"). Claims 1-3 are currently pending. The following remarks are considered by applicant to overcome each of the Examiner's outstanding rejections to current Claims 1-3. An early Notice of Allowance is therefore requested.

I. THE CURRENT OFFICE ACTION IS DEFICIENT AND MUST BE REISSUED

Applicants note that Examiner has failed to address key arguments from Applicant's Amendment/Response filed on July 6, 2009. In particular, Applicant's previously raised the point that **none** of the cited references teach or suggest a treatment which includes **removing** any pathologically changed tissue parts, as required by Claim 1.

While Examiner has cited a new reference (i.e., Gonzalez), this new reference is **not** cited as teaching or suggesting **removing** any pathologically changed tissue parts.

In fact, Examiner's current Office Action refers to **old** language of Claim 1 which states:

> "treating the area of body tissue, wherein the treatment comprises the probe selecting **and/or** removing any pathologically changed tissue parts...."

This is clear from page 3 of the current Office action, in which Examiner asserts that Ciaff discloses a treatment that "comprises the probe selecting **and/or** removing any pathologically changed tissue parts". (emphasis added).

However, Claim 1 was previously amended to state:

> "treating the area of body tissue, wherein the treatment comprises the probe selecting **and** removing any pathologically changed tissue parts...."

In other words, Claim 1 was amended to delete the "or" language, thereby **requiring** that the treatment includes **removing** any pathologically changed tissue parts.

Examiner has failed to address this previously amended language of Claim 1, and Applicants' arguments related thereto. As such, the current Office Action is **deficient**. Therefore, Applicants respectfully assert that Examiner **must** withdraw the current Office Action and issue either (1) a Notice of Allowance, or (2) a **new non-final** Office Action addressing all of Applicant's previous arguments, as well as the arguments of the current Response.

The above issue was discussed with the Examiner during a teleconference held on November 19, 2009, and Examiner **agreed** that the current cited references fail to teach or suggest a treatment that includes **removing** any pathologically changed tissue parts. Accordingly, Examiner indicated that he would perform a further search and either (1) issue a new **Non-Final** Office Action, or (2) issue a Notice of Allowance.

II. SUMMARY OF RELEVANT LAW

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The determination of obviousness rests on whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In determining obviousness, four factors should be weighed: (1) the scope and content of the prior art, (2) the differences between the art and the claims at issue, (3) the level of ordinary skill in the art, and (4) whatever objective evidence may be present. Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. The Examiner carries the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness and must show that the references relied on teach or suggest all of the limitations of the claims.

III. REJECTION OF CLAIMS 1 AND 2 UNDER 35 U.S.C. § 103(A) BASED ON CIAFF IN VIEW OF RAYMOND AND GONZALEZ

On page 2 of the current Office Action, the Examiner rejects Claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Ciaff in view of Raymond and Gonzalez. These rejections are respectfully traversed and believed overcome in view of the following discussion.

A. Claims 1 and 2

Claim 1 states, in part:

> "treating the area of body tissue, wherein the treatment comprises the probe selecting **and removing** any pathologically changed tissue parts...." (emphasis added).

(1) The Cited Reference FAIL to Teach or Suggest Removing Any Pathologically Changed Tissue

Accordingly, as stated above, Claim 1 requires that the treatment includes removing any pathologically changed tissue parts. Examiner asserts that paragraph [0013] of Ciaff discloses this language of Claim 1. However, paragraph [0013] merely states that the device of the invention offers the doctor the possibility of a detailed analysis of the anomalous muscle groups and distinguishing between different forms of neuromuscular anomalies. In fact, paragraph [0013] of Ciaff explicitly states:

> "[0013] Typically, a patient might describe their symptoms in terms of a muscle feeling "a bit weak". Traditionally, the clinician assesses muscular weakness and lack of strength using a grading system of 1 to 5 for strength and movement--or in a more advanced method by isokinetic evaluation. Using conventional diagnostic methods, it has been difficult for Clinicians to **evaluate** whether the problem was lack of strength--or some other finite neuro-muscular problem, eg, whether there was a pain inhibition pattern or a malfunctioning muscle. **The apparatus of the invention** provides the clinician with a more detailed **analysis** of the recruitment behaviour of a muscle group enabling him to distinguish various forms of neuro-muscular anomalie." (emphasis added).

Accordingly, Ciaff relates to **analysis/evaluation** of muscle groups, and **not** to **removal** of tissue. Thus, neither paragraph [0013] nor in any other portion of Ciaff

discloses or renders obvious the selection **and removal** of pathologically altered tissue parts, as required by Claim 1.

Moreover, neither Raymond nor Gonzalez cure this deficiency of Ciaff. More specifically, Raymond relates to **stimulation** of nerves, and **not** to **removal** of tissue. Raymond, Col. 5, Lns. 8-60. Similarly, Gonzalez relates to **stimulation** of the area of dysfunction, spine and head, and **not** to **removal** of tissue. Gonzalez, Col 11, Lns. 40-49.

While the Examiner newly points to Gonzalez as disclosing a solution for testing brain tissue, wherein the tissue is stimulated, defects are corrected, and stimulation is continued until normal function has been established, Gonzalez fails to disclose any **removal** of brain tissue.

More specifically, the solution described in Gonzalez concerns a method for testing, identifying and treating areas of aberrant sensory or motor ability and includes implementation of sensory or motor function tests.

Dysfunctional areas are identified and subsequently stimulated by therapeutic means until no further dysfunction, particularly neurological dysfunction, can be determined by new function tests.

In Gonzalez, the probe is positioned in the organ to be treated, or is moved toward that area, after a diagnostic examination has been carried out (sensory or motor function tests). The tissue selection is carried out by evaluating the stimulus response given by the tissue in question as the result of stimulus by different electric/electronic signals.

In contrast to the solution described in Gonzalez, in which it is attempted to regenerate the diseased tissue by stimulating the nerves leading to the diseased tissue region (see Figure 2A, reference number 32, and column 5, lines 60-65), the diseased tissue is **removed** in the solution of Claim 1. Therapy is merely an additional option in the solution of Claim 1.

While the solution of Gonzalez does relate to application in the brain, Gonzalez is concerned with testing and reanimating brain tissue. Gonzalez does **not** describe a **surgical** procedure to **remove** the pathologically altered tissue, nor is this rendered obvious.

Thus, **none** of the references to which Examiner cites teach or suggest a treatment that comprises the probe selecting **and removing** any pathologically changed tissue parts, as required by Claim 1.

(2) The Cited Reference FAIL to Teach or Suggest Repositioning the Probe When a Pathologically Changed Tissue Part is Detected

Claim 1 also states, in part:

> "wherein, if the tissue stimulation **does not identify a pathologically changed tissue part**, the probe is **repositioned** and a new area of body tissue is stimulated." (emphasis added).

Examiner admits that Ciaff fails to teach or suggest the above claim language. Rather, Examiner points to Raymond (Col. 5, Ln. 8 – Col. 6, Ln. 60) as disclosing the above language of Claim 1.

However, the above language of Claim 1 specifically states that the probe is repositioned **when** the tissue stimulation **does not identify a pathologically changed tissue part**. However, Raymond only **generically** discloses is that the site of stimulation is automatically modified "based on the evaluation of the response" (Raymond, Col. 6, Lns. 23-28), and that the site of stimulation is modified in accordance with a site selecting algorithm "which is based on information provided by a response detecting means and a stimulation input means" (Raymond, Col. 6, Lns. 30-33). In keeping with this **generic** disclosure, Raymond further discloses that the site of subsequent stimulation is automatically modified "based on an evaluation of the tumescence response." Raymond, Col. 6, Lns. 39-41. Such a **generic** disclosure by Raymond fails to disclose the **specific** situation of the probe being repositioned **when** the tissue stimulation **does not identify a pathologically changed tissue part**, as stated in Claim 1.

In response, Examiner asserts that one of skill in the art would have been capable of setting their own standards as to on what the evaluation of the response is based, including testing for defects and/or healthy tissue. However, the **only** suggestion to reposition a probe **when** the tissue stimulation **does not identify a pathologically changed tissue part**, is the current Application **itself**. In other words, Examiner can point to **no** teaching or suggestion in support of his **blind, unsupported** assertion that it would be obvious to reposition the probe **when** the tissue stimulation **does not identify a**

pathologically changed tissue part, as stated in Claim 1. Thus, Examiner's assertions is either (1) unsupported or (2) improperly uses hindsight to find the motivation to modify the teachings of the references in a way that is **only** suggested by the current Application itself. Either way, it is clear that Examiner has failed to properly establish **any** motivation to modify the teachings of the cited references so as to arrive at a method that provides for repositioning the probe **when** the tissue stimulation **does not identify a pathologically changed tissue part**, as stated in Claim 1.

In fact, the reference to which Examiner points as disclosing repositioning a probe (i.e., Raymond) discloses that the multiple sites are **always** stimulated consecutively, **regardless of the response**. The resultant data is then interpreted to discriminate between trends in response states corresponding to periods of successful nerve stimulation and states corresponding to unsuccessful nerve stimulation. Raymond, Col. 5, Lns. 34-51. This is done in order to successfully figure out the proper locations so as to localize the target nerve. See Raymond, Col. 5, Lns. 8-33. Thus, the stimulation cite of Raymond is moved **regardless** of whether or not the stimulation **does not identify a pathologically changed tissue part**. Thus, Raymond certainly fails to teach repositioning the probe **when** the tissue stimulation **does not identify a pathologically changed tissue part**, as stated in Claim 1.

In addition, the portion of Raymond to which Examiner cites relates to stimulation using an **array** of stimulating electrodes. Raymond, Col. 5, Lns. 22-29. These electrodes of the array may be arranged in a multi-dimensional configuration **for activation in successive triplets**. Raymond, Col. 5, Lns. 44-47. As such, Raymond fails to disclose that **any** electrode is actually **repositioned** in order to stimulate a new area of body tissue. Rather, Raymond teaches that a **different** set of electrodes are activated to stimulate different areas of the nerve. Therefore, Raymond fails to disclose a **single** probe which is **repositioned** to stimulate a new area of body tissue, according to Claim 1 above.

In response, Examiner asserts that Raymond discloses alternating the stimulation site based on the evaluation of a response, and that it would therefore be obvious to modify the teaching of Raymond so as to move a single probe, rather than use an array of probes, to stimulate multiple sites.

However, the searching of the nerves in Raymond is limited to a target region which is probably at most the size of the electrode surface at the probe that is used (column 5, line 20). The use of a series of electrodes which is mentioned in the specification (column 5, lines 18-21) also argues against a repositioning of the system.

Thus, the combination of the cited references fails to teach or suggest the above language of Claim 1.

(3) There is NO Motivation to Combine the Teachings of Gonzalez with Those of Ciaff or Raymond

Claim 1 states, in part:

> "placing a probe in an area of **body tissue of a brain** of a body of a person being treated;

Thus, the entire method of Claim 1 relates to treating body tissue **of a brain**. Examiner admits that Ciaff and Raymond fail to disclose treatment of **brain tissue**. Rather, Examiner cites to Gonzalez as disclosing testing brain tissue in an iterative test where tissue is stimulated, corrected of any defects, and re-stimulated/tested until functioning normally. Examiner then asserts that it would have been obvious to modify the methods of Ciaff and Raymond in order to test brain tissue. This, however, misinterprets the teachings of the references.

In particular, the brain is very different from muscle groups or nerve tissue. One of skill in the art knows that treatments that work for muscle tissue or nerve tissue do not necessarily work for brain tissue. As such, there is no reasonable expectation of success that methods of treating muscle tissue or nerve tissue can also be used to treat brain tissue. Thus, according to MPEP § 2143.02, there is **no** motivation to combine the references in the way Examiner suggests.

Accordingly, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of independent Claim 1, and corresponding Claim 2 because it is dependant from independent Claim 1. Therefore, Applicant respectfully requests that Examiner withdraw the rejection of Claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Pub. No. 2003/0100932 to Ciaff in view of U.S. Patent No. 5,775,331 to Raymond et al. and U.S. Patent No. 6,685,729 to Gonzalez.

B. Claim 2

As stated above in relation to Claim 1, Claim 1 depends from Claim 1. As Claim 1 is allowable, so must be Claim 2.

In addition, Claim 2 states, in part:

> "wherein the tissue stimulation that follows the repositioning of the probe can be carried out by iterative or continuous transmission of stimulus signals."

Even with the most sympathetic reading, paragraph [0011] of the specification in Ciaff does not disclose that the tissue selection can be carried out during the repositioning of the probe by iterative or progressive transmission of stimulus signals.

It is true that paragraph [0011] discloses that the control can be carried out in analog or digitally and conveniently by the user. In so doing, programming of certain sequences of pulses is provided in addition to adaptations of the parameters.

In contrast, in the solution of Claim 2 the obtained stimulus response can be used to change the parameters of the next stimulus in order to generate an iterative sequence of stimuli. This cannot be compared to a predetermined series of stimuli as in Ciaff.

Accordingly, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of Claim 2. Therefore, Applicant respectfully requests that Examiner withdraw the rejection of Claim 2 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Pub. No. 2003/0100932 to Ciaff in view of U.S. Patent No. 5,775,331 to Raymond et al. and U.S. Patent No. 6,685,729 to Gonzalez.

IV. REJECTION OF CLAIM 3 UNDER 35 U.S.C. § 103(A) BASED ON CIAFF IN VIEW OF RAYMOND, GONZALEZ, AND ZEALEAR

On page 4 of the current Office Action, the Examiner rejects Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Ciaff in view of Raymond, Gonzalez, and Zealear. This rejection is respectfully traversed and believed overcome in view of the following discussion.

Claim 3 depends from independent Claim 1. As Claim 1 is allowable, so must be Claim 3.

In addition, Claim 3 states, in part:

> "wherein (a) a direct **online** tissue stimulation is carried out by alternating **treatment** and positioning with tissue stimulation and immediate evaluation of the stimulus responses and, (b) during treatment of critical tissue regions, a user is warned and/or the treatment can be interrupted." (emphasis added).

Zealear fails to disclose this feature of Claim 3 or render it obvious.

Further, none of the references, including Zealear, disclose a solution for tissue-selective treatment in therapy **and surgery** (i.e., the **removal** of pathologically changed tissue parts **required** during the **treatment** of Claim 1).

In the solution of Claim 3 (which includes all of the limitations of Claim 1), a probe is positioned in the region of the pathological change after it is placed on the body organ or body tissue to be treated, and the tissue selection is activated in that different preadjustable or modulatable electrical and/or electromagnetic stimulus signals are sent to the tissue to stimulate it. By evaluating the responses to these stimuli, the healthy tissue parts can be distinguished from the pathologically changed tissue parts. When the stimulus response indicates an expected, healthy tissue, the probe is repositioned and the tissue selection is reactivated. When no stimulus response or an unexpected stimulus response indicating pathologically altered tissue is received, the appropriate surgical treatment is carried out by **the same probe** at the selected location.

In contrast, Ciaff, Raymond, and Gonzales are directed to solutions by which muscle cells or nerve cells are stimulated, on the one hand, to test for healthy functioning and, on the other hand, to restore healthy functioning that is no longer present.

While the solution of Zealear is directed to the field of surgery, only a **monitoring** of the nervous system during the surgical procedure is carried out in the proposed solution in order to prevent injury to the nervous system.

In contrast to the references cited by the Examiner, the appropriate **surgical treatment** of the detected pathologically altered tissue (i.e., removal) is carried out by means of **the same probe** in the solution claimed by us.

As such, the probe can be used immediately for surgical treatment at the site of application after pathologically altered tissue has been detected and thus obviates a time-consuming changing and repositioning of the probe.

The method according to the invention for tissue-selective therapeutic and surgical treatment, particularly in the brain, makes it possible to separate certain pathologically altered tissue parts (e.g., tumors) from the remaining, healthy tissue parts (e.g., nerves, tendons) and to fragment and/or suck out these pathologically altered tissue parts without damaging the healthy tissue parts.

Accordingly, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of Claim 3. Therefore, Applicant respectfully requests that Examiner withdraw the rejection of Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Pub. No. 2003/0100932 to Ciaff in view of U.S. Patent No. 5,775,331 to Raymond et al. and U.S. Patent No. 6,685,729 to Gonzalez, and further in view of U.S. Patent No. 4,817,628 to Zealear et al.

Based upon the above remarks, Applicant respectfully requests reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

Eugene LeDonne – Reg. No. 35,930
Joseph W. Treloar – Reg. No. 60,975
REEDSMITH LLP
599 Lexington Avenue
New York, NY 10022
Tel.: 212.521.5400

EL:JWT

500343.20238